## REMARKS

Claims 1, 3-10, 12-21, and 23-27 are currently pending in the application. Claims 11 and 22 are cancelled herein. Claim 1 has been amended to recite that the composition is a "once daily sustained release" composition. Support for "once daily" is found, e.g., at par. [0039], line 1. Support for "sustained release" is found, e.g., at paragraphs [0098], [0100], [0103], all at line 1. See also paragraph [0002]. Claim 1 has also been amended to recite that the composition comprises a "starch" and a "hydrophilic polymer". Support is found at paragraph [0052]. Claim 1 has also been amended to recite "wherein said composition comprises a full daily dose contained in a single dosage unit, further wherein said composition, when administered once daily, exhibits a bioavailability substantially equivalent to an equal daily dose of an immediate-release pramipexole dihydrochloride reference formulation administered three times a day". These limitations were found in claims 11 and 22, which are cancelled herein. Finally, claims 3 to 7 have been amended to correct their dependency and make them depend from claim 1, and withdrawn claim 26 has been amended to make it depend from claim 1. No new matter has been added. Entry of these amendments is therefore respectfully requested.

In view of the remarks below, Applicants respectfully request reconsideration and withdrawal of the rejections set forth in the February 19, 2009 Office Action.

### Interview

Applicants wish to thank the Examiner for the courtesy extended during the telephone interview of July 15, 2009. During the interview, the rejection under 35 U.S.C. 103 was discussed. The substance of the interview is included in the remarks regarding this rejection below.

### Rejection Under 35 USC § 112

Claims 3-7 stand rejected under 35 USC § 112, second paragraph, as indefinite for improperly depending from cancelled claim 2. Claims 3-7 have been amended to depend from claim 1. Withdrawal of this rejection is respectfully requested.

### Rejection For Double Patenting

Claims 1-16, and 18-25 are provisionally rejected for non-statutory obviousness-type double patenting as being unpatentable over Claims 1-23 of co-pending Application Serial No. 10/626,166 ("the '166 Application"). An appropriately signed terminal disclaimer is being concurrently filed by mail.

**Rejection Under 35 USC § 103(a)**

Claims 1 and 3-25 stand rejected as obvious under 35 U.S.C. §103(a) over United States Patent Application Publication No. 2002/0103240 to Pospisilik ("Pospisilik") in view of United States Patent No. 6,197,339 to Ju ("Ju"). In view of the amendments to the claims and the remarks below, applicants respectfully traverse the rejection with respect to pending claims 1, 3-10, 12-21, and 23-25.

The claims have been amended to more clearly distinguish the art cited by the Examiner. In particular, as amended claim 1 now recites that the claimed composition comprises a starch and a hydrophilic polymer. It has also been amended to recite that the composition is a once daily sustained release composition, that it comprises a full daily dose contained in a single dosage unit, and that the composition, when administered once daily, exhibits a bioavailability substantially equivalent to an equal daily dose of an immediate-release pramipexole dihydrochloride reference formulation administered three times a day. It is respectfully submitted that properly read, the cited references do not suggest the invention as claimed.

The Ju reference is relied on for a teaching to modify the teaching of Pospisilik to arrive at the invention. In order to accomplish this with respect to claim 1 as amended, the reference must provide a suggestion and reasonable expectation of success of obtaining a sustained release pramipexole composition containing starch and a hydrophilic polymer which when administered once daily achieves the bioavailability substantially equivalent to an equal daily dose of an immediate-release pramipexole dihydrochloride formulation administered three times a day. It is submitted that it is not appropriate to read the reference (or the primary reference) as providing this teaching.

Ju teaches a formulation containing a starch and hydrophilic polymer which "permits" twice daily dosing of sumanirole (Abstract). There is no disclosure of once daily dosing of sumanirole in this type of formulation.

The Examiner notes that Ju discloses that the exact dosing and frequency depends on the severity of the condition, weight and general physical condition of the patient, and other factors. (Col. 3, line 45)

However, Ju also teaches (in the sentence immediately preceding the portion cited) that "It is preferred that the daily dose be divided into two equal amounts since the sustained release tablet formulation adequately maintains blood levels when administered twice daily." (Col. 3, lines 41-44)

It is submitted that this disclosure, when read as a whole, cannot properly be interpreted as a teaching to modify Pospisilik to arrive at successful administration of pramipexole in a once daily formulation using starch and hydrophilic polymer.

Furthermore, claim 1 now requires that the composition administered once daily achieve bioavailability substantially equivalent to an equal daily dose of immediate-release pramipexole dihydrochloride formulation administered three times a day. Ju, instead, teaches that adequate blood levels (of sumanirole) are maintained using these ingredients when administered twice daily. There is no suggestion that adequate blood levels (of sumanirole) were achievable when administered once daily.

Ju does teach that dosing can be adjusted for the patient. But it does not, it is submitted, properly teach that the composition described can be modified to obtain once daily administration which achieves bioavailability substantially equivalent to an equal daily dose of pramipexole dihydrochloride formulation administered three times a day.

Finally, the teaching in the Abstract of the Ju reference that the formulation taught "permits" twice daily dosing can not, it is submitted, be properly ignored. Read as a whole, the reference does not teach a formulation containing the recited ingredients for successful administration of pramipexole once daily which achieves bioavailability substantially equivalent to an equal daily dose of pramipexole dihydrochloride formulation administered three times a day.

For these reasons, Applicants respectfully request the withdrawal of the rejection of claims 1, 3-10, 12-21, and 23-25 under 35 U.S.C. §103(a) over Pospisilik in view of Ju.

**Withdrawn Methods Claims 26-27**

In the event the composition claims 1, 3-10, 12-21, and 23-25 are found allowable, Applicants respectfully request rejoinder of the dependent method claims 26-27 under USPTO's Rejoinder Practice as outlined in MPEP § 821.04.

**Conclusion**

In view of the remarks above, Applicants respectfully submit that the pending claims are allowable, and request issuance of a notice to that effect. If a telephone interview is deemed to helpful, the Examiner is invited to contact applicants' undersigned attorney.

Respectfully submitted,

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